Blood-Stream Infection (CDC)

From: Lynn Hadaway [lynn@hadawayassociates.com]
Sent: Thursday, December 03, 2009 12:40 PM
To: Blood-Stream Infection (CDC)
Subject: Comments on new draft for Intravascular Catheter Related Infections
Attachments: Intermittent sets.pdf; ATT66849.htm; ManuscriptGalleyNeedleless Connector.pdf; ATT66850.htm

Thank you for this opportunity to provide comments.
I do like the new format with the guideline statements and the background information placed together.

I do have the following questions.
1. The document continually refers to 2% chlorhexidine, yet there are 2 preparations on the market in the US - 2% and 3.15%. Does this constant reference to only 2% indicate that the higher percentage products are not appropriate for use? Or is this reference to only 2% based on the lack of studies for the higher percentage product. Also I would recommend that you include a complete description of this skin antiseptic agent - chlorhexidine gluconate in isopropyl alcohol. The tincture products are the only ones on the market in the US as opposed to all other countries that have access to aqueous products of many different strengths.

2. Page 14, line 318 and 319 - the statement about hand veins having a lower risk of phlebitis. The referenced study is greater than 10 years old. I would like to bring to your attention another study that quantifies the risk associated with use of hand and wrist veins. Infiltration and extravasation injuries occur more frequently in this area of joint flexion. I realize phlebitis has a greater connection to infection, however this document should not encourage use of veins in areas of joint flexion when we have a good understanding of the additional risk from those sites. My reference is
Kagel E, Rayan G. Intravenous catheter complications in the hand and forearm. Journal of Trauma. 2004;56:123-127.

3. The document makes reference in several places to the complication of infiltration of IV fluids. In some places the word "infiltration" is used while other places uses the word "extravasation". According to the Infusion Nurses Society Standards of Practice, these words have differing meanings. Infiltration is the inadvertent escape of non-vesciant fluids/medications while extravasation is the inadvertent escape of vesicant fluids/medications. My recommendation would be use follow the INS definitions for these terms or choose one and use it consistently throughout this document.

4. Page 32 discussion of catheter lock solutions. The use of any form of alcohol to lock a catheter can cause damage to some formulations of polyurethane catheters. I am not aware of any catheter manufacturers that have statements in their instructions for use stating that locking a polyurethane catheter is acceptable. There are studies showing that some newer formulations of polyurethane can tolerate alcohol and those manufacturers will usually provide a letter about the use of alcohol for skin cleaning. However the use of alcohol to lock any polyurethane catheter for extended periods could be a problem. This issue should be addressed if any form of alcohol is to be recommended by this paper.

5. Page 32, line 733. All hospital pharmacies may not meet the requirements for compounding. Compounding pharmacy would be a more accurate term for this sentenc.

6. Page 45, line 1014 and page 48, line 1074. Both pages refer to "wiping" the diaphragm or access port. This is far too little information about this critical step. We also know that friction is a critical component of any cleaning technique for any needleless connector or injection port. How long should this cleaning be - 5, 10, 15, or 30 seconds? Does this make a difference? Is one simple wipe sufficient? Should your statement encourage the use of friction for mechanical cleaning as well? Is drying time an issue? Where is the evidence that supports the action of chlorhexidine gluconate on plastic surfaces? We know that CHG binds to skin cells making it effectiveness better with use, but does the same thing happen on plastic?

7. Page 48, line 1090 "Nonsterile tape used to fix the needle to the port" Because of OSHA bloodborne pathogen standard we do not use needles for the purpose of connecting tubing pieces together. Also, the Infusion Nursing Standards of Practice states that the only acceptable means of tubing junction securement is luer locks. Tape should never be used as it poses a risk of harboring organisms near these junction.

8. The entire discussion of needleless connectors on page 49 is confusing. I have coauthored an article calling for standardized use of terms associated with these devices. I have attached the galley proof of this article with permission of the editor, Mary Alexander. "Needleless system" is a broad term that encompasses many other devices. Needleless connector is a better term and is used by ECRI. None of these devices exert any pressure. They simply displace fluid, therefore they are NOT positive pressure devices. They are positive displacement devices. Line 1109 calls for appropriate disinfection, yet that has not been defined. The work by Rutala would seem to imply that we can not successfully "disinfect" these devices because they fall into the critical category of devices which require caustic agents for disinfection, agents that can not be used on a device while connected to the patient. My reference is:

Rutala W, ed. Disinfection, Sterlization and Antisepsis: Principles, Practices, Current Issues and New Research. Washington, DC: Association for Professionals in Infection Control and Epidemiology, Inc; 2007.

9. page 46 on replacement of administration sets. The CDC documents have never made a distinction between primary continuous administration sets and primary intermittent administration sets. This causes much confusion for nurses and pharmacists. All studies on administration sets have purposefully excluded the sets used intermittently, or those sets that are connected and disconnected with each dose of medication. This could be a connection to the primary continuous set or directly to the needleless connector on the catheter hub. Nursing practice with the management of the male luer end of these intermittently used sets has never received adequate attention. I have attached an article documenting the abysmal practices with these sets. Many are totally uncovered or nurses will attempt to clean the contaminated male luer end rather than replacing the set. I know this document states that needleless connectors should only be accessed with sterile devices, but this statement is not sufficient with regard to these sets. Many facilities will follow the practice of changing these intermittent sets no more frequently than 72 hours as stated in the last set of guidelines. Once the male luer end has been connected and disconnected repeatedly over 3, now to be 4 days, there is no possible way it will remain sterile. However, the CDC makes no distinction in the uses of these sets so it is assumed that all sets are the same. My article calls attention to the many problems with this practice.

The Institute for Safe Medication Practices has also called attention to this issue at http://www.ismp.org/Newsletters/nursing/Issues/NurseAdviseERR200711.pdf. I realize the absence of studies on this issue prohibits making a recommendation. At the very least, I would request that the authors consider making a statement about the change frequency for administration sets used intermittently by connection and disconnection is unknown and label it as an unresolved issue. We are so concerned about the needleless connectors and their associated risk for BSI, yet there is virtually no attention paid to the use of these contaminated sets over 3 or 4 days. The risk of BSI from these needleless connectors will only be reduce when we pay adequate attention to both sides of this connection.

10. page 56. The comment column for midline catheters still includes catheters made of elastomeric hydrogel. This catheter material is no longer sold as those products were removed from the market in 1996. These anaphylactoid reactions have also been reported with other types of midline catheters and with PICCs.

Thank you for this opportunity. Please let me know if I can answer any questions about my comments.